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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,784	08/28/2001	Joseph A. Haslwanter	0T0426KQ3	6530

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	//

DATE MAILED: 01/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,784	HASLWANTER ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Amendment filed 08/28/01, Information Disclosure Statement, and Terminal Disclaimer filed 01/13/03.

Terminal Disclaimer

The terminal disclaimer filed on 01/13/03 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of USPN 5,897,858 and USPN 6,316,483 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

Claims 15-17, and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al. US 4,728,509, in view of Gilbert et al. US 5,116,847 and Parnell US 5,015,474.

Shimizu teaches nasal aqueous liquid preparation having pH between 5 and 8, the formulation comprising drug and 0.2-20 % (w/v) of polyvinylpyrrolidone (PVP) having average MW of about 25,000-120,000, cyclodextrin, phosphate buffer, propylene

glycol, benzyl alcohol, sodium phosphate, and thickener (columns 1-2, and examples 2-3).

Shimizu is silent as to the teaching of the specific drug, and other carriers as claimed in claims 2-8.

Gilbert teaches nasal spray composition comprising active agent, such as chlorpheniramine maleate, oxymetazoline hydrochloride; benzalkonium chloride; polyethylene glycol; and solubilizing agent such as cyclodextrin (columns 6-8).

Shimizu does not teach the use of two or more PVP.

Parnell teaches nasal spray composition comprising drug, preservative, benzyl alcohol, polyethylene glycol, PVP as thickener, EDTA, and buffer (columns 4-5). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Shimizu's formulation with the active drug, and the aqueous carriers in view of the teachings of Gilbert, and PVP as thickening agent in view of the teaching of Parnell to obtain the claimed invention, because the references teach the advantageous results in the use of aqueous nasal formulation useful for the treatment of respiratory diseases, such as allergy, itchy nose, and runny nose. The expected result would be an aqueous nasal spray formulation comprising oxymetazoline HCl and PVP that is stable, alleviate dryness, and reduce nose-irritation.

Claims 18-20, and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al., in view of Gilbert et al., Parnell, and Rybacki et al. (Library of a Pharmacist, vol. 7).

Shimizu, Gilbert, and Parnell are relied upon for the reason stated above. The references are silent as to the specific molecular weight of PVP being claimed.

Rybacki teaches PVP having molecular weight of about 10,000, 40,000, 160,000, and 360,000 are useful in pharmaceutical art as a binder, solubilizer, and thickener (pages 8-10). Thus, it would have been obvious for one of ordinary skill in this art to modify Gilbert's formulation using PVP having the molecular weight of Rybacki with the expectation of at least similar result, because the references teach the advantageous results in the use of PVP in liquid nasal formulation.

Response to Arguments

Applicant's arguments filed 01/13/03 have been fully considered but they are not persuasive.

Applicant argues that discloses the use of polyvinylpyrrolidone, cyclodextrin or caffeine as a solubilizer for a particular polycyclic drug compound, and therefore, cannot be considered to establish any obviousness of the claims. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is noted the claims upon which applicant argues are composition (product) claims, and therefore, the patentability of the product claims does not depend on how the polyvinylpyrrolidone is being used.

Applicant argues that Gilbert teaches compositions of the opiate agonist drug loperamide, for topical application; Parnell describes topical compositions that are useful for relieving dryness of mucosal membranes. However, it is not at all apparent how one skilled in the art could make any meaningful combination of teachings from the combining Shimizu et al., Gilbert et al., and Parnell. In response to applicant's argument that, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Shimizu teaches a nasal aqueous composition comprising polyvinylpyrrolidone, benzyl alcohol, propylene glycol, buffer, and an anti-histamine compound (drug). Gilbert specifically teaches a nasal liquid composition comprising solubilizing agent, benzalkonium chloride, polyethylene glycol, and loperamide. Although Gilbert teaches the use of loperamide as an active drug, Gilbert further teaches the inclusion of other active drugs, including an anti-histamine and decongestant agents, such as, chlorpheniramine maleate and oxymetazoline (column 7, lines 26 through column 8, lines 1-11). Parnell teaches liquid nasal composition for the treatment of allergic diseases comprising antioxidant, polyethylene glycol, buffer, active agent, and polyvinylpyrrolidone. Thus, it is the position of the examiner that all three references, Shimizu, Gilbert, and Parnell do teach/suggest liquid nasal composition comprising antihistamine/anti-allergy drug useful in pharmaceutical art, and therefore,

the obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Koochaki et al. and Geria are cited as of interest for the teachings of liquid nasal formulation comprising oxymetazoline HCl.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600